The updated version of Charlson Comorbidity Index (CCI), for predicting resource utilisation, was never considered in such studies.

PRM60

THE PEDIATRIC ASTHMA PATIENT REGISTRY IN IMPLEMENTATION OF LONG TERM FOLLOW UP

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OBJECTIVES: The randomized clinical trials (RCT), as gold standard for evidence-based medicine, have a number of shortcomings, and their results do not fully reflect actual clinical practice. In cases where RCTs are difficult to conduct because of ethical or other aspects, data bases of clinical cases - medical registries are used to determine the effectiveness and safety of any medical intervention in long-term observation. Due to heterogeneity of clinical symptoms in different groups of patients with bronchial asthma (BA), to assess the efficacy and safety of treatment of severe persistent uncontrolled asthma in the real clinical practice, the best practice is to use a long-term clinical monitoring. Aim - to create patient registry for children and adolescents with severe persistent uncontrolled BA. **METHODS:** By experts of center in the result of system work software was created. It was shell for management of database of clinical cases – patient registry of children with uncontrolled severe persistent BA, who received Omalizumab as addition to basis therapy. **RESULTS:** The database included information about 64 children (62.5% boys) from 6 to 17 y 11 mo (mean age 12.9 y) with severe persistent uncontrolled BA, who received / receive (31 patients, 70.9% boys) bioengineered treatment (duration of treatment from 1 till 70 mo). During the analyzed period of treatment safety of Omalizumab was confirmed: more than 5384 injections were conducted. Local adverse events were registered at frequency of 1/100 and were manifested as light redness, induration and light edema, were realized in 1-1.5 days after Omalizumab administration. Local allergic reactions such as rash were observed in two patients and were stopped by antihistamines **CONCLUSIONS:** The patient registry will help in solving problems as epidemiological, and in order to achieve optimal endpoints for monitoring and analysis of efficacy and safety of innovative high-tech medications and approaches which have been used previously for long time.

PRM61

THE NATIONWIDE OSMED HEALTH-DB DATABASE. A TOOL TO SUPPORT HEALTHCARE DECISION-MAKING AND REAL-WORLD EVIDENCE GENERATION

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OBJECTIVES: Since 2012, the Italian Medicines Agency (AIFA-Agenzia Italiana del Farmaco), with the cooperation of CliCon, has been providing and updating the OsMed Health-DB Database, a nationwide standardized monitoring system to provide analyses, reports, and trends on appropriateness of medicines' use and medication persistence, to inform decision-makers in order to improve health outcomes and to avoid wasting of health-care resources **METHODS:** The OsMed Health-DB Database has two main components with distinct but complementary functions: a data-warehouse, a repository containing the integrated demographic, pharmaceutical and hospital discharges administrative data kept by Local Health Units (LHUs) and Regional Health Units (RHUs) and a dashboard, a set of performance indicators, with updates scheduled every six months, evaluating the prescription adherence to preset standards of some chronic pathologies at the local, regional, and national level. In 2014, 36 LHUs and 5 RHUs provided data, covering all Italian Regions and the data-warehouse stored information of about 30 million patients (almost the 50.0% of the entire Italian population). **RESULTS:** The 2014 OsMed Report reported the trend of 34 indicators on appropriateness and adherence of 10 chronic diseases: hypertension, hypercholesterolemia, diabetes mellitus, COPD, osteoporosis, depression, ulcers and esophagitis, anemia, psoriasis and rheumatoid arthritis. The average age of the LHU sample resulted 44.0 years versus 43.7 years of the Italian population. The percentage of males resulted 48.5%, in accordance with the national data available. Medication persistence rate for all studied diseases averaged 43.3%, with a range of 13.9% of respiratory system drugs and 62.2% of anti-diabetic drugs. Results will be reported on "National Report on medicines use in Italy" available at AIFA website. **CONCLUSIONS:** Findings from the OsMed Health-DB Database highlighted that the majority of indicators is changing toward appropriateness and adherence. These findings prove that continuous monitoring of appropriateness and adherence is a driver for improving real-world use of medicines.

PRM62

DEVELOPMENT OF AN INTERNATIONAL OBSERVATIONAL STUDY PROGRAMME TO DESCRIBE THE MANAGEMENT AND OUTCOMES OF MILD STROKE AND TRANSIENT ISCHAEMIC ATTACK IN ROUTINE CLINICAL PRACTICE

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OBJECTIVES: Patients with mild stroke or transient ischaemic attack (TIA) are at high risk of recurrent stroke and other cardiovascular events. The Assessment of Real-world Evidence in Stroke/TIA (ARES) programme aims to characterize the management and outcomes of patients with mild stroke/TIA in real-world clinical practice using the most suitable data sources. **METHODS:** In an initial Systematic Understanding of Real-world Evidence (SURE) assessment, suitable data sources (cohorts, registries and databases) were identified and characterized by systematic literature and web searches supplemented with e-mail and telephone contact. Data sources were recommended if they were active, representative, accessible, recorded National Institutes of Health Stroke Scale (NIHSS) scores or ABCD2 scores, and reported health resource utilization, ischaemic events and death during follow-up of at least 90 days (either direct or via linkage). The programme of included studies was finalized with input from principal investigators. **RESULTS:** More than 2900 publications and 300 websites were screened, and 16 registries, 17 cohort studies and 43 databases were reviewed. Nine data sources from seven countries were recommended, of which six complementary sources were included: Get With The Guidelines-Stroke in the USA (an in-hospital database including about 1600 hospitals); National Stroke Registry in China (132 hospitals); Fukuoka Stroke Registry in Japan (seven stroke centres); Clinical Research Centre for Stroke – 5thDivision Registry in South Korea (12 stroke centres); Riks-Stroke in Sweden (all Swedish hospitals admitting patients with acute stroke); and Erlangen Stroke Registry in Germany (Erlanger community). Based on a globally agreed study design concept, protocols for each data source have been developed locally and are now being implemented. **CONCLUSIONS:** The ARES programme will provide global, observational data from contemporary populations with mild stroke/TIA in real-world clinical practice. Studies will be presented individually owing to differences in the nature of the data sources.

PRM63

HEALTH TECHNOLOGY ASSESSMENT NEEDS INFORMATION TECHNOLOGY: THE EXPERIENCE FROM THE FIRST ITALIAN STUDY ON THE DA VINCI SURGICAL ROBOT

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OBJECTIVES: Health Technology Assessment of innovative biomedical devices still requires the effort to introduce dedicated Information Technology tools able to support the implementation of the evaluation process. The aim of the study was to systematize the collection, the management and the analysis of large volumes of multidimensional data in order to optimally conduct an HTA study of emerging technologies. **METHODS:** We designed a relational database, subsequently we developed and implemented a centralized, web-based user-friendly data entry for Case Report Form (CRF) data collection. (i) The development of User Interface (UI), (ii) data anonymization, (iii) differentiate accesses, (iv) automated quality control checks for data entry, (v) appropriate system tables to make data entry uniform, and (vi) the possibility of creating final reports were addressed. In the data extraction phase, we used MySQL computer languages and combined PHP and HTML codes. Knowledge Discovery in Data process was implemented with different software and programming languages for automation of the data collection, extraction and analysis. **RESULTS:** The IT tools have been applied to the first multicenter prospective Italian study of HTA on the da Vinci surgical system, obtaining meaningful end points in terms of costs and clinical outcomes. The study involved the enrolment of 699 patients from the 8 Italian Teaching Hospitals in the period 2011-2014. Patients were enrolled and prospectively evaluated from the preoperative work-up till six months after the discharge. **CONCLUSIONS:** The IT tools developed allow researchers to more efficiently and effectively manage large volumes of various source of HTA data, enhancing data quality from storage to processing. The database design could be empowered and readjusted for other HTA studies in near future and the entire approach generalized. In the immature field of HTA of innovative biomedical devices, this example of application could promote the automation of the implementation process of HTA.

PRM64

MANAGEMENT OF SOFT TISSUE SARCOMA (STS) IN FRANCE - A RETROSPECTIVE ANALYSIS OF THE FRENCH CLINICAL BIOLOGICAL SARCOMA DATABASE (GSF-GETO)

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OBJECTIVES: The primary objective is to describe how patients with advanced STS are managed in France. The secondary objectives are to describe the epidemiological characteristics, the diagnostic procedures as well as the therapeutic strategy for the management of patients with STS. **METHODS:** This observational, retrospective and national study will use the patient databases of the European CONTICANET "CONnective TIssue Cancer NETwork" network and of the French networks: RRePS and NetSarc(Pathological and Clinical Reference Networks for Soft Tissues and Visceral Sarcomas) . All the data collected in these networks and compiled in the "Sarcoma clinicobiological database" will allow good national representativity of STS. The study period was defined to reflect the current situation in terms of diagnosis and disease management in France. **RESULTS:** The European database currently contains data from 12,485 patients (pts) registered by the French Sarcoma Group centers with 9,736 soft tissues and visceral sarcomas. Data from STS patients, who were diagnosed between 2012 and 2013, will be extracted from the Conticabase database. Part of these data will be "chained" with the shared database from the French networks RRePS (24,000 pts) and NetSarc (28,000 pts). Results are expected at the end of 2015. **CONCLUSIONS:** This pharmacoepidemiological study shows how useful high-quality medical databases are to study rare diseases and their management in real life. This study is carried out as part of a public/private partnership.

PRM65

THE REMOTE MONITORING TECHNOLOGIES IN THE PATIENT RISK MANAGEMENT

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OBJECTIVES: Due to high prevalence of socially significant chronic diseases among children the introduction of information technologies in the process of interaction between doctor and patient is important. The aim: to analyze the prospects of the development of remote monitoring systems, to identify their shortcomings and to propose solutions. **METHODS:** The review had included 36 publications, 1 meta-analysis concerning telemedicine from 2001 to 2014 y. In the evaluated studies the following questions were explored: • research of social and economic aspects of

telemedicine (evaluation of usefulness); • the view of information systems or architectures. The following characteristics were taken: • purpose of the system; • interaction of patients and physicians; • training and impact on lifestyle - the formation of health-preserving behaviors (with the exception of smoking, adequate physical activity, etc.); • self-management. **RESULTS:** The following problems of implementation of telemedicine systems were identified: • high cost, the need to purchase special equipment and devices; • the need for training and motivation of both staff and patients; • lack of a unified architecture, protocol stack and hardware-software platform for the integration of systems at all stages of the process - from data collection to its processing, decision-making and patient feedback. Despite the fair amount of existing telemonitiring systems almost all of its provide only data collection, while the entire analytical part falls on the doctor. Almost all of studies were focused on the elderly and adults. **CONCLUSIONS:** A promising direction is the development of a prototype system for remote health monitoring in pediatric patients. The study was supported by the Russian Foundation for Basic Research, the project ¹ 13-04-12055.

PRM66

USING MACHINE LEARNING TO POPULATE A MARKOV MODEL BY MINING BIG DATA DIRECTLY FROM HOSPITAL EHRS – AN APPLICATION TO DYNAMICALLY PREDICT HOSPITAL-ACQUIRED PRESSURE ULCERS

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OBJECTIVES: Real-world big data accessible through electronic health record (EHR) systems offer opportunities to collect generalizable information to populate economic models. Using a supervised machine learning approach, the objectives were: (a) to mine a hospital EHR for transition probabilities of high-risk patients for developing hospital-acquired pressure ulcers (HAPUs); and (b) to compare efficiency and accuracy of predictive methods between Markov modeling and Bayesian inference with EHR data. **METHODS:** This study used a de-identified panel of patient hospitalizations since 2010 in a U.S. tertiary academic medical center EHR to study Braden scores of patient risk for developing HAPUs. The study focused on patients hospitalized for ≥5 days and at least two Braden scores. Braden scores were converted from an ordered scale into five categories (i.e. minimal risk; at risk; moderate risk; high risk; very high risk). A 10-stage Markov model was constructed via supervised machine learning using R software designating the five Braden categories as transition states, as well as end-states for discharge or HAPU incidence. Results of the Markov approach were age-adjusted and compared to prior probabilities of HAPU risk derived from naïve and full Bayesian inference. Measures of computational accuracy and efficiency were derived to compare analytical approaches. **RESULTS:** The EHR provided a panel of over 34,787 patients. The Markov model yielded transition probabilities for each of 7 transitions. Patient risk for developing a HAPU is highly predictable after approximately 4-6 iterations. The very high-risk cohort had a clinically meaningful increase in risk for HAPU development of 2.35% compared to a minimal risk transition probability of 0.05% ($p<0.001$). Neither of the Bayesian classifiers provided accurate comparisons. **CONCLUSIONS:** Real-world big data from an EHR enables outcomes researchers to mine transition probabilities using supervised machine learning. These results can be obtained to efficiently populate Markov models for cost-effectiveness and decision analysis.

PRM67

BURDEN OF EPILEPSY IN COLOMBIA

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OBJECTIVES: Epilepsy lays an important burden on healthcare systems and society in general. Disability adjusted life years (DALYs) have been developed to compare the burden of this disease both between conditions and between geographical boundaries. With improving data on disease incidence and prevalence in Colombia, we can refine our DALYs-based estimates. **METHODS:** Using different strategies, including the official healthcare provision database (called RIPS) and death certificates, as well as extrapolation from published neuroepidemiologic studies, we estimated the incidence and prevalence by age groups, the disease duration and the attributable mortality. Base don previous studies, we assumed an average disability weight of 0.113. With this information, and using the classic methodology described by Murray & Lopez, we calculated DALYs for the year 2012. **RESULTS:** 49,984 (10.4%) of the 479,836 Colombian epilepsy patients are in the 15-19 year-old group. Overall, it was found that epilepsy was responsible for 0.88% of all deaths (12,837) in Colombia, 8,219 (64%) of them in 60-year olds or older. A total of 5.25 DALYs per 1,000 person-years are lost due to epilepsy in Colombia, 75% of which (3.91 DALYs) are due to premature mortality, with a higher burden in men (6.12 DALYs) than in women (4.41 DALYs). **CONCLUSIONS:** We reported new estimations on epilepsy incidence and prevalence by age groups in Colombia and conclude that DALYs lost due to epilepsy in Colombia are almost double the previous figure, mostly because of the underestimation of attributable mortality. With this figure, epilepsy ranks 12th instead of 19th in the list of the most important causes of DALYs lost.

RESEARCH ON METHODS – Modeling Methods

PRM68

GENERALIZED IMPLEMENTATION OF EM ALGORITHM FOR ESTIMATION OF TRANSITION PROBABILITY MATRIX

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OBJECTIVES: Health economic models typically follow a Markovian framework with discrete health states. The transition probability matrix (TPM), which characterizes the health state transitions, is the key driver of such a model. Estimation of TPM depends upon the observation intervals of clinical studies and the model cycle length. Generally Maximum-Likelihood (ML) or eigen-decomposition method can be used to estimate the TPM. However, these methods are not feasible for studies with non-uniform observation intervals (e.g., observations taken at 1, 3 & 6 months), or when eigenvalues are negative or complex. The current objective is to provide a generalized algorithm to estimate TPM in all possible situations using all the available data. **METHODS:** Craig & Sendi (2002) illustrated an EM algorithm approach to estimate 1 month TPM for a 3-state model, where 1 and 2 month observations were available. We generalized this procedure and created an algorithm for any observation intervals and any number of states. We evaluated this algorithm in the following situations: i) Observations at multiple intervals to estimate a single cycle TPM, ii) Seventh month observed transitions to estimate a 2-month TPM when the eigenvalues are complex, iii) Sixth month observed transitions to estimate a 2-month TPM when the eigenvalues are negative. **RESULTS:** The generalized EM algorithm approach replicated results obtained from ML and eigen-decomposition method. In cases where eigenvalues were negative and complex, this method provided solutions which were valid and interpretable. In all three situations mentioned above, the generalized EM algorithm produced consistent and valid results. **CONCLUSIONS:** A generalized EM algorithm can be a useful tool to estimate TPM, in complex situations where ML estimation and eigen-decomposition cannot be used. It allows the use of all the observed data to estimate the TPM, thus increasing the accuracy of the health economic models.

PRM69

PATIENT HETEROGENEITY IN COST-EFFECTIVENESS MODELS FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD): ARE CURRENT MODELS SUITABLE TO EVALUATE PERSONALIZED MEDICINE

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OBJECTIVES: To assess how suitable current COPD cost-effectiveness models are to evaluate personalized treatment options for COPD by exploring the type of heterogeneity included in current models and by validating outcomes for subgroups of patients. **METHODS:** A consortium of COPD modelling groups participated in three evaluations. First, they reported all patient characteristics included in the model and provided the level of detail in which the input parameters were specified. Second, groups simulated disease progression, mortality, QALYs and costs for hypothetical subgroups of patients that differed in gender, age, smoking status and FEV1% predicted. Finally, model outcomes for exacerbations and mortality for subgroups of patients were validated against published subgroup results of two large COPD trials. **RESULTS:** Nine COPD modelling groups participated. Most models included gender (7), age (9), smoking status (6) and FEV1% predicted (9), mainly to specify disease progression and mortality. Almost all input parameters were specified by FEV1% predicted. In addition, disease progression was higher for females and smokers in three and five models, respectively and costs were higher for older patients in three models. Differences between subgroups on other parameters were more variable between the models. Trial results showed higher exacerbation rates for females, which was found in one model, higher mortality rates for males (found in two models), lower mortality for younger patients (found in four models), and higher exacerbation and mortality rates in severe COPD compared to moderate COPD patients (found in four models). **CONCLUSIONS:** The majority of currently available COPD cost-effectiveness models are able to evaluate the cost-effectiveness of personalized treatment based on gender, age, smoking and FEV1% predicted. Treatment in COPD is however, more likely to be personalized based on clinical parameters. Two models include several clinical patient characteristics and seem most suitable to evaluate personalized treatment, although some important clinical parameters are still missing.

PRM70

MODELING THE BURDEN OF ABDOMINAL AORTIC ANEURYSM (AAA) IN EUROPE IN 2013

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OBJECTIVES: To estimate the number of prevalent cases of abdominal aortic aneurysm (AAA) and deaths attributable to AAA in five major European Union (5EU) markets: France, Germany, Italy, Spain, and the United Kingdom (UK). **METHODS:** We used disease modeling software, DisMod II (World Health Organization), to assess AAA burden via a multi-state life table where differential equations define relationships between incidence, prevalence, and disease-specific mortality. Market-specific input data included age- and sex-specific population structure, age- and sex-specific all-cause mortality, and cubic spline interpolation of size- and sex-specific AAA prevalence. Other input data consisted of relative risk (RR) estimates of death for persons with AAA compared with persons without AAA, adjusted for age, ethnicity, height, weight, smoking, and cardiovascular disease history. **RESULTS:** We estimated 2,484,058 prevalent cases in the 5EU in 2013 (90% CI: 2,282,702–2,638,106), resulting in 48,805 deaths attributable to AAA (90% CI: 39,924–54,291). In the combined 5EU, females accounted for 20.2% of prevalent cases and 43.2% of deaths. France had the lowest number of prevalent cases (581.8 per 100,000 population) and deaths (11.0 per 100,000 population) among the 5EU markets, while Italy had the highest number of prevalent cases (1,103.7 per 100,000 population) and deaths (22.3 per 100,000 population). The number of